K080624

510(k) Summary of Safety and Effectiveness for NavStationIrad EMT

APR 11 2008

I. Manufacture

CAS innovations AG
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Germany

II. Contact Person:

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III. Device Name and Classification:

Trade Name:	NavStationIrad EMT
Common Name:	Computer assisted, image-guided surgery system
Classification Name:	Computer Tomography X-ray System
Classification Panel:	Interventional Radiology
CFR Section:	21 CFR 892.1750
Device Class:	Class II
Device Code:	JAK

IV. Date Prepared

March 19, 2008

V. Device Description

The navigation system NavStationIrad EMT is a software and hardware tool to plan different trajectories to selected targets and to place tools (e.g. biopsy needles) with navigation control inside the selected targets. The navigation system can be used within the scope of interventional radiology.

Navigation System:

The navigation station consists of an industrial PC with integrated touch screen as user interface and dedicated navigation software. The PC is mounted on a mobile rack. For image acquisition the navigation system is connected to a C-arm system with CT option. For the communication of the navigation system with the imaging system, a DICOM network application using the DICOM standard protocol is used.

In order to place the patient safe and comfortable on the intervention table we use a patient fixation device BodyFix Medical Intelligence (510(k) Number: K001052).

In order to track navigation devices the electromagnetic (EM) tracking system is used. The EM tracking system consists of a field generator producing an alternating electromagnetic field for operation. The EM field induces a voltage in small coils implemented in the tips of the tracked navigation devices. The voltage is measured by the EM tracking system and used to calculate the current position and orientation of the coil inside the EM field thus determining the sensor coordinates in five degrees of freedom (DoF).

The navigation hardware (PC, Monitor, Rack and tracking system) are combined to NaviBase. NaviBase is a CE labeled hardware and software platform for all navigation systems of CAS innovations and part of this technical file.

Navigation Devices:

As devices electro-magnetic-needles with small coils embedded in their tips are used.

For image-to-patient registration a patient panel/reference panel (PP) is used. With the panel it is possible to map the patient image space to the physical space. This procedure is called registration.

To control residual patient motion, an additional tracked device (skin marker/skin sensor) is used. The tracking system is able to detect the sensor and send its position relative to the PP to the navigation system. The patient motion is visualized at the monitor and the physician is able to recognize the motion and can react on it accordingly.

VI. Intended Use

NavStationIrad EMT is intended to be an intraoperative image guided computer assisted navigation system for minimally invasive interventions for interventional radiology. NavStationIrad EMT can be used in combination with imaging systems that create a 3D based model of the anatomy, like Computer Tomography (CT) or C-Arm systems.

It displays the simulated image of a tracked device (needle) on a computer monitor screen that shows images of anatomic relevant regions of the patient. The system also allows the planning of trajectories and displays the planning information together with the simulated image of a tracked needle on a computer monitor screen. At the same time movements of the patient are taking into account.

The device is intended for use in clinical applications and for anatomic structures where computer tomography or c-arm is currently used for visualizing such devices.

VI. Substantial Equivalence

NavStationIrad EMT is substantially equivalent to the following FDA cleared frameless stereotaxic systems:

Manufacturer	System Name	510(k) approval number
Traxtal Technologies	ABARIS	K053610
UltraGuide Ltd.	UltraGude CT-Guide	K002258
	UltraGude 1000	K974432
Medtronic	StealthStation FluoroNav	K990214

The device labeling contains instructions for use, the indication for use, clinical workflow, cautions, contraindications, warnings, and planning guidance. All information assures safe and effective use of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

CAS Innovations AG,
% Mr. Stefan Preiss
TÜV America, Inc.
Product Service
1775 Old Highway 8 NW, Suite 104
NEW BRIGHTON MN 55112-1891

APR 11 2008

Re: K080624
Trade/Device Name: NavStation/RAD EMT
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: February 22, 2008
Received: March 5, 2008

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080624

Device Name: NavStationIRad EMT

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NavStationIrad EMT is intended to be an intraoperative image guided computer assisted navigation system for minimally invasive interventions for interventional radiology. NavStationIrad EMT can be used in combination with imaging systems that create a 3D-based model of the anatomy, like Computer Tomography (CT) or C-Arm systems.

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The device is intended for use in clinical applications and for anatomic structures where computer tomography or c-arm is currently used for visualizing such devices.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K080624